REMARKS

The applicants have studied the Office Action dated December 28, 2006. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 36-59 are pending and claims 53 and 59 have been amended. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

The applicants would like to thank the Examiner for his time during the telephonic interview which took place on April 5, 2007. During the interview, the Examiner and applicants' representative discussed the Teissen-Simony reference in relation to the "obvious reversal of parts" argument raised by the Examiner in the Office Action. The Examiner agreed with the contention of the applicants' representative, but also required submission of a more detailed response that would allow the Examiner to conduct a new search.

The Examiner objected to claims 53 and 59 for reciting limitations without providing sufficient antecedent basis. The applicants have made amendments to claims 53 and 59 to provide sufficient antecedent basis. Accordingly, applicants respectfully request that the objections to claims 53 and 59 be withdrawn.

Claims 36-39, 41-44, 46-51, 53-56 and 58-59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,522,803 to Teissen-Simony. These rejections are respectfully traversed.

Embodiments of the present invention are directed to an improved insertion set for transcutaneous placement of a sensor in a patient and/or transcutaneous delivery of a fluid to a patient. In particular embodiments, the insertion set includes a mounting base adapted for mounting onto the patient's skin. The insertion set also includes a cannula coupled to the mounting base and having a distal end protruding from the mounting base. The cannula is adapted for transcutaneous placement on the patient, and preferably, also transcutaneous delivery of fluid, such as medication, to the patient. The mounting base further includes at least one

resilient latch arm projecting from the mounting base, which is adapted for releasable engagement with at least one corresponding recess on a connector for infusion tubing used in conjunction with the insertion set.

One key aspect of the presently claimed embodiment is the resilient latch arm(s) which projects from the mounting base and facilitates releasable engagement of the mounting base with the connector. The independent claims recite the "the mounting base includes at least one resilient latch arm projecting from the mounting base and adapted for releasable engagement with the at least one recess on the connector." In order to disconnect or reconnect the mounting base and the connector, the patient is required to disengage or re-engage only the latch arm(s) on the mounting base, and simply move the connector away or toward the mounting base. It is easier for the patient to hold the mounting base and maneuver the latch arm(s) on the mounting base because the mounting base is stabilized on the patient's skin. Such a latch mechanism for releasable engagement of the mounting base with the connector is especially useful for patients with dexterity problems.

As discussed during the April 5, 2007 interview with the Examiner, the applicants feel that the claims distinguish over the Teissen-Simony reference. The Teissen-Simony reference is directed to an infusion set having resilient latch arms on the connector and recesses on the mounting base. The Examiner explains in paragraph 10 of the Office Action that it would have been obvious to one having ordinary skill in the art to reverse the parts and place the resilient latch arms on the mounting base and recesses on the connector, as recited in the claims. However, the applicants urge the Examiner to reconsider this argument in view of the factors discussed during the interview and detailed in these remarks.

An important advantage of the claimed design, as described above, is providing ease of use for patients with dexterity problems. Diabetes is a disease that affects many patients, older and younger, in various ways. In particular, patients with dexterity problems would find it difficult to utilize the infusion set described in Teissen-Simony because pressing in the latch arms on the freely moving connector might potentially cause the infusion set to be dislodged. In contrast, if the latch arms are placed on the mounting base, as recited in the claims, patients with

dexterity problems would find it easier to handle because the mounting base is stabilized on the patient (i.e., with an adhesive patch). Therefore, the patient could disengage the latch arms on the mounting base, while at the same time moving the connector and infusion tubing away from the mounting base, without the fear of dislodging the infusion set from their body.

Although the design recited in the claims provides the advantages listed above, other considerations must be observed to assure a safe and usable device is created—in particular, a simple reversal of parts does not necessarily create a functional device as argued by the Examiner. The first consideration is that when the connector and mounting base are disconnected, the latch arms on the mounting base are exposed and can potentially snag on pieces of clothing. This is an important consideration because the potential of snagging may unnecessarily bother and/or hurt the patient. Another consideration is that removing the latch arms from the connector on the Teissen-Simony reference exposes the needle on the connector (see Fig 13, needle 40 and col. 6, lines 17-29). If the needle is exposed, the patient has no protection from inadvertently pricking themselves when they attempt to reconnect the connector/tubing with the mounting base. This leads to the next consideration—if one chose to move the needle to the mounting base (where it could be protected by the latch arms) the fear of snagging worsens because items might possibly snag on the needle and/or the latch arms. Additionally, if the needle is placed on the mounting base, foreign bodies could enter the mounting base and seep into the patient's infusion site.

All of these considerations must be examined prior to creating a usable and functional device of the type described in the claims. Accordingly, merely reversing the parts on the Teissen-Simony reference would not lead one having ordinary skill in the art to the claimed invention. In fact, if one having ordinary skill in the art did reverse the parts on the Teissen-Simony reference, the resulting device would be unusable and nonfunctional based on the considerations discussed above.

Therefore, it is respectfully submitted that the rejection of claims 36-59 under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5003 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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